United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

Mr. Ravi Jaiswal
President and Chief Executive Officer
MCM Services Group LLC
1301 Corporate Center Drive
Suite 180
Eagan, MN 55121

Dear Mr. Jaiswal:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

The Commission and its staff have a longstanding interest in attorney advertising and solicitation. Although the FTC has opposed overly-broad restrictions that prevent the communication of truthful and non-misleading information, unfair or deceptive advertising by lawyers violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Moreover, deceptive attorney advertising that has an effect on drug or device sales violates Section 12(a)(2) of the FTC Act, 15 U.S.C. § 52(a)(2). An advertisement is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and if it is material—that is, if the ad is likely to affect a consumer's conduct or decision with regard to a product or service.[1]

The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled

[1] *See Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984). To determine whether an advertising claim is deceptive, the FTC examines the entirety of the ad, not isolated excerpts, and considers the net impression the ad conveys from the perspective of the audience to whom it is directed. *Id.*

or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that three of your lawsuit ads may convey deceptive claims. One Gold Shield Group ad concerns the Type 2 diabetes medications Invokana, Invokamet, Jardiance, and Farxiga. A voiceover states, in part:

> Attention, Type 2 diabetics. Invokana, Invokamet, Jardiance, and Farxiga are linked to an increased risk of toe, leg, and foot amputations. The FDA has also warned of links to genital gangrene, also known as Fournier's gangrene or ketoacidosis. People who suffered serious side effects after taking these Type 2 diabetes drugs may be entitled to a cash award.

Viewers may take away from this ad that the FDA has warned that taking Invokana, Invokamet, Jardiance, or Farxiga poses a substantial risk of gangrene of the genitals. We note that the FDA describes gangrene of the genital area as a rare side effect.[2] Accordingly, the implication that these products pose a substantial risk of gangrene of the genital area appears to be false. In addition, this ad may convey to a significant number of viewers that taking Invokana, Invokamet, Jardiance, or Farxiga poses a substantial risk of toe, leg, and foot amputations and that the risk of the risks from taking these medicines outweigh their benefits. Unless you have competent and reliable scientific evidence to support such claims, you should not make them.

The Gold Shield Group ad about Abilify also may be deceptive. A voiceover states, in part:

> If you know someone who has an uncontrollable gambling problem, it may not be their fault. The Food and Drug Administration is now warning that Abilify can cause uncontrollable gambling.... You may be entitled to a cash award. Time to file a claim is limited.

Viewers may take away from this ad that the FDA has warned that taking Abilify poses a substantial risk of uncontrollable gambling. We note that the FDA has stated that the reported impulse-control problems from Abilify, including an uncontrollable urge to gamble, are rare.[3]

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[2] FDA, *FDA Warns about Rare Occurrences of a Serious Infection of the Genital Area with SGLT2 Inhibitors for Diabetes* (Aug. 29, 2018), *available at* www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrences-serious-infection-genital-area-sglt2-inhibitors-diabetes.

[3] FDA, *FDA Drug Safety Communication: FDA Warns about New Impulse-Control Problems Associated with Mental Health Drug Aripiprazole (Abilify, Abilify Maintena, Aristada)* (May 3, 2016), *available at* www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-about-new-impulse-control-problems-associated-mental-health.

Accordingly, the implication that Abilify poses a substantial risk of uncontrollable gambling appears to be false. In addition, this ad may convey that the risks from taking Abilify outweigh its benefits. Such a claim would require competent and reliable scientific evidence.

We also are concerned about the Gold Shield Group ad about Tasigna. The ad prominently displays the phrase "Leukemia Drug Alert!" while a voiceover says:

> People with chronic myeloid leukemia who took Tasigna may be at an increased risk for atherosclerosis and coronary artery disease. These conditions often result in poor circulation, which can lead to limb amputation, serious blood clots, heart attack, stroke, and death.

This ad may imply that the risks to patients taking Tasigna outweighs the benefits the drug provides. Again, unless you have competent and reliable scientific evidence to support such a claim, you should not make it.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[4] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician. Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

Finally, lawsuit ads that open with sensational warnings or alerts may initially mislead consumers about the ads' sponsor. Two of the ads quoted above reference FDA warnings; one begins, "Attention, Type 2 diabetics"; and another flashes the phrase "Leukemia Drug Alert!" on-screen. Reasonable consumers might interpret ads with these elements as government-sanctioned medical alerts or other types of public service announcements. The Commission's Enforcement Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[5]

We strongly encourage you to review your advertising to ensure that it is not unfair or deceptive. We will continue to monitor for potentially unfair or deceptive lawyer advertising and take follow-up action as warranted.

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[4] There are several elements to an unfairness determination. 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).

[5] *See* www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf.

Thank you for your attention to this matter. Please direct any inquiries concerning this letter to Richard Cleland at rcleland@ftc.gov or at (202) 326-3088.

Very truly yours,

Mary K. Engle

Mary K. Engle
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

Mr. Bill Tilley
Chief Executive Officer
Amicus Legal Group, LLC
26650 The Old Road
Suite 212
Valencia, CA 91381

Dear Mr. Tilley:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

The Commission and its staff have a longstanding interest in attorney advertising and solicitation. Although the FTC has opposed overly-broad restrictions that prevent the communication of truthful and non-misleading information, unfair or deceptive advertising by lawyers violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Moreover, deceptive attorney advertising that has an effect on drug or device sales violates Section 12(a)(2) of the FTC Act, 15 U.S.C. § 52(a)(2). An advertisement is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and if it is material—that is, if the ad is likely to affect a consumer's conduct or decision with regard to a product or service.[1]

The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the

[1] *See Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984). To determine whether an advertising claim is deceptive, the FTC examines the entirety of the ad, not isolated excerpts, and considers the net impression the ad conveys from the perspective of the audience to whom it is directed. *Id.*

FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that your lawsuit ad about the medications Xarelto and Pradaxa[2] may convey deceptive claims. The Amicus Legal Group ad at issue opens with the prominent on-screen statement, "ATTENTION XARELTO & PRADAXA DRUG WARNING." A voiceover says, in part:

> Attention. If you or a loved one is one of the millions of Americans prescribed the blood thinner medications Xarelto or Pradaxa, listen closely. You could be at serious risk. Xarelto and Pradaxa may be linked to significant internal bleeding, stroke, and even death. At least one report estimates tens of thousands will suffer major bleeding events requiring hospitalization and more than four thousand may bleed to death after taking Xarelto.

This ad may imply that taking Xarelto and Pradaxa poses substantial risks of internal bleeding, stroke, and death, and that the risks of taking these medications outweigh their benefits. Unless you have competent and reliable scientific evidence to support such claims, you should not make them.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[3] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician. Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

Finally, lawsuit ads that open with sensational warnings or alerts may initially mislead consumers about the ads' sponsor. Your ad begins with a prominent "DRUG WARNING," a call to "Attention," and a warning that consumers who take Xarelto or Pradaxa "could be at serious risk." Reasonable consumers might interpret an ad with these elements as a government-sanctioned medical alert or another type of public service announcement. The Commission's Enforcement Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[4]

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[2] This advertisement is available at https://www.ispot.tv/ad/A4hK/amicus-media-group-xarelto-and-pradaxa-warning.

[3] There are several elements to an unfairness determination. 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).

[4] *See* www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf.

We strongly encourage you to review your advertising to ensure that it is not unfair or deceptive. We will continue to monitor for potentially unfair or deceptive lawyer advertising and take follow-up action as warranted.

Thank you for your attention to this matter. Please direct any inquiries concerning this letter to Richard Cleland at rcleland@ftc.gov or at (202) 326-3088.

Very truly yours,

Mary K. Engle

Mary K. Engle
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

Brian Ketterer, Esq.
Managing Partner
Ketterer Browne & Anderson
336 South Main Street
Suite 2D-C
Bel Air, MD 21014

Dear Mr. Ketterer:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

The Commission and its staff have a longstanding interest in attorney advertising and solicitation. Although the FTC has opposed overly-broad restrictions that prevent the communication of truthful and non-misleading information, unfair or deceptive advertising by lawyers violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Moreover, deceptive attorney advertising that has an effect on drug or device sales violates Section 12(a)(2) of the FTC Act, 15 U.S.C. § 52(a)(2). An advertisement is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and if it is material—that is, if the ad is likely to affect a consumer's conduct or decision with regard to a product or service.[1]

The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the

[1] *See Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984). To determine whether an advertising claim is deceptive, the FTC examines the entirety of the ad, not isolated excerpts, and considers the net impression the ad conveys from the perspective of the audience to whom it is directed. *Id.*

FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that your lawsuit ad about the diabetes medication Invokana[2] may convey deceptive claims. The Ketterer Browne & Anderson ad at issue states, in part:

> Attention, people with diabetes! The FDA has just issued a warning that Invokana may cause an increased risk of amputations. If this has happened to you or a loved one, call right now. You may be entitled to substantial compensation.

Viewers may take away from this ad that FDA has warned that patients taking Invokana should stop taking the drug. We note that the FDA has advised patients not to stop taking their diabetes medicine without first talking to their health care professional.[3] Accordingly, the implication that FDA has warned patients to stop taking Invokana appears to be false. In addition, this ad may convey to a significant number of viewers that taking Invokana poses a substantial risk of amputations, and that the risk of taking it outweighs its benefits. Unless you have competent and reliable scientific evidence for such claims, you should not make them.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[4] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician.[5] Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

Finally, lawsuit ads that open with sensational warnings or alerts may initially mislead consumers about the ads' sponsor. Your ad begins, "Attention, people with diabetes! The FDA has just issued a warning that Invokana may cause an increased risk of amputations." Reasonable consumers might interpret an ad with this language as a government-sanctioned medical alert or another type of public service announcement. The Commission's Enforcement

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[2] This advertisement is available at https://www.ispot.tv/ad/dIhF/kba-attorneys-invokana.

[3] FDA, *FDA Drug Safety Communication: FDA Confirms Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin (Invokana, Invokamet, Invokamet XR)* (May 26, 2017), *available at* www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-confirms-increased-risk-leg-and-foot-amputations-diabetes-medicine.

[4] There are several elements to an unfairness determination. 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).

[5] We do not consider your ad's textual disclosure that consumers should not stop taking a prescribed medication without consulting their doctor to be clear and conspicuous.

Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[6]

We strongly encourage you to review your advertising to ensure that it is not unfair or deceptive. We will continue to monitor for potentially unfair or deceptive lawyer advertising and take follow-up action as warranted.

Thank you for your attention to this matter. Please direct any inquiries concerning this letter to Richard Cleland at rcleland@ftc.gov or at (202) 326-3088.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

[6] *See* www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf.

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

Mr. Travis Marble
Managing Director
Lucy Business Services, LLC
110 Camerota Way
Redwood City, CA 94065

Dear Mr. Marble:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

The Commission and its staff have a longstanding interest in attorney advertising and solicitation. Although the FTC has opposed overly-broad restrictions that prevent the communication of truthful and non-misleading information, unfair or deceptive advertising by lawyers violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Moreover, deceptive attorney advertising that has an effect on drug or device sales violates Section 12(a)(2) of the FTC Act, 15 U.S.C. § 52(a)(2). An advertisement is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and if it is material—that is, if the ad is likely to affect a consumer's conduct or decision with regard to a product or service.[1]

The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of

[1] *See Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984). To determine whether an advertising claim is deceptive, the FTC examines the entirety of the ad, not isolated excerpts, and considers the net impression the ad conveys from the perspective of the audience to whom it is directed. *Id.*

these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that a number of your lawsuit ads may convey deceptive claims. A Knightline Legal ad about proton-pump inhibitors (PPIs) such as Nexium, Prilosec, or Prevacid opens with an onscreen statement, "STOMACH CANCER WARNING." The announcer states, in part:

> If you or a loved one used a proton pump inhibitor such as Nexium, Prilosec, or Prevacid and then developed stomach cancer, call right now.... A recent medical study found that the prolonged use of both prescription and over-the-counter proton-pump inhibitors may double a patient's risk of developing stomach cancer. Thousands of acid reflux patients may have been exposed to serious risk by these dangerous medications.

Viewers may take away from this ad that a medical study establishes that prolonged use of both prescription and over-the-counter PPIs doubles a patient's risk of developing stomach cancer and therefore poses a substantial risk of stomach cancer. We note that the study referenced in the ad found that PPI use was associated with an additional 4.29 gastric cancer cases per 10,000 people per year, amounting to a very small, .043-percent increase in risk.[2] Accordingly, the implication that the study establishes that prolonged use of PPIs poses a substantial risk of stomach cancer appears to be false. The advertisement also may imply that the risks of taking Nexium, Prilosec, or Prevacid outweigh their benefits. Unless you have competent and reliable scientific evidence to support such a claim, you should not make it.

Two other Knightline Legal advertisements—one about Valsartan, the other about Invokana and Jardiance—may present similar concerns.[3] Screenshots from the Valsartan ad state, "VALSARTAN CANCER VICTIMS" and "If you or a loved one were prescribed Valsartan to treat High Blood Pressure and were later diagnosed with Cancer or Kidney Damage, CALL RIGHT NOW!" Screenshots from the Invokana/Jardiance ad state, "ATTENTION

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[2] Ka Shing Cheung & Wai K. Leung, *Long-Term Use of Proton-Pump Inhibitors and Risk of Fastric Cancer: A Review of the Current Evidence*, 12 Therap. Adv. Gastroenterol. 1, 4 (2019).

[3] The ads had been posted to https://www.ispot.tv/ad/otUM/knightline-legal-valsartan-cancer-victims and https://www.ispot.tv/ad/oTLN/knightline-legal-invokana-and-jardiance-law-suit but are no longer available for viewing. Our comments are based on screenshots from the ads.

DIABETICS!," "TYPE 2 DIABETES MEDICATIONS," "GANGRENE VICTIMS," and "If you or a loved one took Invokana and Jardiance or any other SGLT2 Inhibitor Drug and were later diagnosed with Fourier's gangrene of the genitals, CALL RIGHT NOW." These two ads may convey claims that taking the referenced medications pose substantial risks of serious diseases or health conditions, and the risks of taking these medications outweigh their benefits. Unless you have competent and reliable scientific evidence to support such claims, you should not make them.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[4] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician.[5] Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

Finally, lawsuit ads that open with sensational warnings or alerts may initially mislead consumers about the ads' sponsor. For example, your ad about proton-pump inhibitors begins "STOMACH CANCER WARNING." Reasonable consumers might interpret the ad to be a government-sanctioned medical alert or another type of public service announcement. The Commission's Enforcement Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[6]

We strongly urge you to review all of your lawsuit ads and ensure that your claims are supported by competent and reliable scientific evidence, you are not unfairly encouraging viewers to discontinue their medications, and you are not misleading consumers about your ads' sponsor. Violations of the FTC Act may result in legal action seeking a federal district court injunction or an administrative cease and desist order. An order also may require you to disgorge ill-gotten gains.

With regard to the advertising claims and other concerns discussed above, please notify Assistant Director Richard Cleland, via electronic mail at rcleland@ftc.gov within fifteen working days of receipt of this letter, of the specific actions you have taken to address FTC

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[4] There are several elements to an unfairness determination. 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).

[5] We do not consider your ads' textual disclosures that consumers should not stop taking a prescribed medication without consulting their doctor to be clear and conspicuous.

[6] *See* www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf.

staff's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

David Matthews, Esq.
Matthews and Associates
2905 Sackett Street
Houston, TX 77098

Dear Mr. Matthews:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

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The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads

[1] *See Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984). To determine whether an advertising claim is deceptive, the FTC examines the entirety of the ad, not isolated excerpts, and considers the net impression the ad conveys from the perspective of the audience to whom it is directed. *Id.*

about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that your lawsuit ad about SGLT2 inhibitors for Type 2 diabetes, including Invokana and Invokamet,[2] may convey deceptive claims. The Matthews and Associates ad at issue states, in part:

> Amputations, gangrene of the limbs or genitals, and ketoacidosis have been associated with the use of Invokana and Invokamet, medications used to treat Type 2 diabetes. If you or someone you love has been diagnosed with one of these conditions, you may be entitled to compensation. The FDA announced that final results from two large clinical trials showed patients using SGLT2 inhibitors, including Invokana and Invokamet, were about twice as likely to develop gangrene requiring leg and foot amputations, mostly affecting the toes. The FDA also warned that patients, both men and women, who use Invokana, Invokamet, and other SGLT2 inhibitors to treat Type 2 diabetes have an increased risk of developing gangrene of the genitals.

Viewers may take away from this ad that the FDA has warned that taking SGLT2 inhibitors, including Invokana and Invokamet, poses a substantial risk of gangrene of the genitals. We note that the FDA describes gangrene of the genital area as a rare side effect.[3] Accordingly, the implication that these products pose a substantial risk of gangrene of the genital area appears to be false. In addition, this ad may convey to a significant number of viewers that taking SGLT2 inhibitors poses a substantial risk of toe, leg, and foot amputations and that the risks from taking these medicines outweigh their benefits. Unless you have competent and reliable scientific evidence to support such claims, you should not make them.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[4] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician. Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

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[2] This advertisement is available at https://www.ispot.tv/ad/dW7y/matthews-and-associates-type-2-diabetes-medications.

[3] FDA, *FDA Warns about Rare Occurrences of a Serious Infection of the Genital Area with SGLT2 Inhibitors for Diabetes* (Aug. 29, 2018), *available at* www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrences-serious-infection-genital-area-sglt2-inhibitors-diabetes.

[4] There are several elements to an unfairness determination. 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).

We strongly encourage you to review your advertising to ensure that it is not unfair or deceptive. We will continue to monitor for potentially unfair or deceptive lawyer advertising and take follow-up action as warranted.

Thank you for your attention to this matter. Please direct any inquiries concerning this letter to Richard Cleland at rcleland@ftc.gov or at (202) 326-3088.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

Adam Pulaski, Esq.
Pulaski Law Firm PLLC
2925 Richmond Avenue
Suite 1725
Houston, TX 77098

Dear Mr. Pulaski:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

The Commission and its staff have a longstanding interest in attorney advertising and solicitation. Although the FTC has opposed overly-broad restrictions that prevent the communication of truthful and non-misleading information, unfair or deceptive advertising by lawyers violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Moreover, deceptive attorney advertising that has an effect on drug or device sales violates Section 12(a)(2) of the FTC Act, 15 U.S.C. § 52(a)(2). An advertisement is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and if it is material—that is, if the ad is likely to affect a consumer's conduct or decision with regard to a product or service.[1]

The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads

[1] *See Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.*, 103 F.T.C. 110, 174-83 (1984). To determine whether an advertising claim is deceptive, the FTC examines the entirety of the ad, not isolated excerpts, and considers the net impression the ad conveys from the perspective of the audience to whom it is directed. *Id.*

about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that your lawsuit ad about the diabetes medications Invokana and Invokamet[2] may convey deceptive claims. The Pulaski Law Firm ad at issue opens with the prominent on-screen statement, "TYPE 2 DIABETES WARNING INVOKANA – AMPUTATION," and then a voiceover says, in part:

> Attention. This is an important Type 2 diabetes warning. If you or a loved one took Invokana or Invokamet for diabetes and suffered an amputation of toes, feet or legs, call…. Based on new data from two large clinical trials, the FDA has concluded that the Type 2 diabetes medicines Invokana, Invokamet, and InvokametXR causes an increased risk of leg and foot amputations.

Viewers may take away from this ad that FDA has warned that patients taking Invokana should stop taking the drug. We note that the FDA has advised patients not to stop taking their diabetes medicine without first talking to their health care professional.[3] Accordingly, the implication that FDA has warned patients to stop taking Invokana appears to be false. In addition, this ad may convey to a significant number of viewers that taking Invokana and Invokamet pose a substantial risk of leg, foot, and toe amputations, and that the risk of taking them outweighs their benefits. Unless you have competent and reliable scientific evidence for such claims, you should not make them.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[4] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician.[5] Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

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[2] This advertisement is available at https://www.ispot.tv/ad/woxN/pulaski-law-firm-diabetes-warning-amputation.

[3] FDA, *FDA Drug Safety Communication: FDA Confirms Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin (Invokana, Invokamet, Invokamet XR)* (May 26, 2017), *available at* www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-confirms-increased-risk-leg-and-foot-amputations-diabetes-medicine.

[4] There are several elements to an unfairness determination. 15 U.S.C. § 45(n); *see also Federal Trade Commission Policy Statement on Unfairness, appended to Int'l Harvester Co.*, 104 F.T.C. 949, 1070-76 (1984).

[5] We do not consider your ad's textual disclosure that consumers should not stop taking a prescribed medication without consulting their doctor to be clear and conspicuous.

Finally, lawsuit ads that open with sensational warnings or alerts may initially mislead consumers about the ads' sponsor. Your ad begins with prominent audio and visual Type 2 diabetes "warnings" and then references the FDA in connection with leg and foot amputations. Reasonable consumers might interpret an ad with these elements as a government-sanctioned medical alert or another type of public service announcement. The Commission's Enforcement Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[6]

We strongly encourage you to review your advertising to ensure that it is not unfair or deceptive. We will continue to monitor for potentially unfair or deceptive lawyer advertising and take follow-up action as warranted.

Thank you for your attention to this matter. Please direct any inquiries concerning this letter to Richard Cleland at rcleland@ftc.gov or at (202) 326-3088.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

[6] *See* www.ftc.gov/system/files/documents/public_statements/896923/151222deceptiveenforcement.pdf.

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 19, 2019

Ricky A. LeBlanc, Esq.
Managing Partner
Sokolove Law, LLC
1330 Boylston Street
Suite 400
Chestnut Hill, MA 02467

Dear Mr. LeBlanc:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you have run ads that may be deceptive or unfair in violation of the FTC Act.

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The staff of the FTC's Division of Advertising Practices recently reviewed numerous attorney television advertisements soliciting potential clients for personal injury lawsuits against manufacturers of pharmaceutical drugs and medical devices (hereafter "lawsuit ads"). Some of these lawsuit ads may misrepresent the risks associated with the treatment and could leave consumers with the false impressions that: (1) their doctor-prescribed drugs have been recalled or cause harms that outweigh their benefits; or (2) the ads constitute public "medical alerts" or have been approved by the Food and Drug Administration ("FDA"). We also understand that the

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FDA's Adverse Event Reporting System contains reports of consumers who viewed lawsuit ads about the prescribed drugs they were taking, discontinued those medications, and then suffered adverse consequences.

We are concerned that your lawsuit ad about the diabetes medication Invokana[2] may convey deceptive claims. The Sokolove Law ad at issue opens with the prominent on-screen statement, "Invokana Warning The FDA warns that Invokana is linked to an increased risk of amputations." A voiceover says, in part:

> Attention, diabetics. The FDA warns that the Type 2 diabetes drug Invokana is linked to an increased risk of leg and foot amputations.

Viewers may take away from this ad that FDA has warned that patients taking Invokana should stop taking the drug. We note that the FDA has advised patients not to stop taking their diabetes medicine without first talking to their health care professional.[3] Accordingly, the implication that FDA has warned patients to stop taking Invokana appears to be false. In addition, this ad may convey to a significant number of viewers that taking Invokana poses a substantial risk of leg, foot, and toe amputations, and that the risk of taking it outweighs its benefits. Unless you have competent and reliable scientific evidence for such claims, you should not make them.

Moreover, in some circumstances, a lawsuit ad that causes or is likely to cause viewers to discontinue their medications may constitute an unfair act or practice.[4] To prevent consumer injury in this scenario, an ad might need to disclose, clearly and conspicuously, that consumers should not discontinue their medications without seeking the advice of their physician. Given the significant health and safety risks of discontinuing prescribed medication, such a disclosure should be easily noticeable, use unambiguous language, and be made both audibly and visually.

Finally, lawsuit ads that open with sensational warnings or alerts may initially mislead consumers about the ads' sponsor. Your ad begins with prominent audio and visual Type 2 diabetes "warnings" and then references the FDA in connection with leg and foot amputations. Reasonable consumers might interpret an ad with these elements as a government-sanctioned medical alert or another type of public service announcement. The Commission's Enforcement Policy Statement on Deceptively Formatted Advertisements explains how established consumer protection principles apply to different advertising formats and affirms the long-standing

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[2] This advertisement is available at https://www.ispot.tv/ad/dqqo/sokolove-law-invokana-amputations#.

[3] FDA, *FDA Drug Safety Communication: FDA Confirms Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin (Invokana, Invokamet, Invokamet XR)* (May 26, 2017), *available at* www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-confirms-increased-risk-leg-and-foot-amputations-diabetes-medicine.

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principle that advertisements and promotional messages promoting goods or services should be identifiable as advertising from the beginning.[5]

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Mary K. Engle
Associate Director
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